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Amd. Dated December 29, 2004

**REMARKS**

Reconsideration is respectfully requested in view of the above amendments and the following remarks. Claim 10 has been amended to incorporate the limitations recited in claim 16. Claims 11-15 and 17 have been amended to correctly recite claim dependencies. Claim 16 has been canceled without prejudice or disclaimer. Claims 10-15 and 17 are pending.

Applicants hereby submit an article showing the effectiveness of the chewing-gum of the claimed invention. The effectiveness of the chewing gum is shown within the attached article "Effect of different chewing gum on plaque accumulation in vivo", which states that the result demonstrated that the chewing gums containing grains of coated silica determined a significant reduction of the plaque indexes (781, English Summary).

The article provides comparative tests between a chewing gum according to the claimed invention, namely the product DAYGUM MICROTECH, which is manufactured according to the claimed invention. The following chewing gums were tested (A) a chewing gum containing the enzymatic system peroxidase which produces hypothiocyanate; (B) a chewing gum containing zinc citrate; (C) a chewing gum according to the invention, including hydrated silica coated with a shell of calcium alginate (4% by weight); (D) a chewing gum containing the same formulation of chewing gum C, without hydrated silica; and (E) control (no chewing).

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Twelve individuals participated in the experimental test. Each individual was introduced twice in each group and in the control group. The individuals were instructed to take two chewing gums dragee after breakfast, lunch, afternoon snack and dinner.

The plaque index was measured according to the Turesky Plaque index modified and the obtained data was evaluated using the Student T test.

The results (pg. 780, right column) show that after twenty-four hours, the plaque indexes were the following:

- A: plaque index average 2.48, standard deviation 0.78
- B: plaque index average 2.63, standard deviation 0.75
- C: plaque index average 2.04, standard deviation 0.74
- D: plaque index average 2.66, standard deviation 0.74
- E: plaque index average 3.06, standard deviation 0.94

Using the Newman-Kuels test for the analysis of the multiple independent parameter data with a significance level of p lower than 0.05, it is apparent that group C (chewing gum according to the present invention) is significantly different from group E and from groups A, B and D. The results show that the results of the action of the granules of hydrated silica encapsulated in a calcium alginate shell (4 % by weight) provides a reduction of the plaque index of 33.3% with respect to the control, whereas the other sugar-free chewing-gum dragee lead to a reduction of the same index between 13% and 17%.

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**Claim rejections - 35 U.S.C. § 103**

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskewitz (US 5,629,035) in view of Yang et al. (EP 0 202 819). Applicants respectfully traverse the rejection.

Claim 10 is directed to a chewing gum composition including a water insoluble abrasive filler substance encapsulated in microspheres of cross-linked alginate, the microspheres comprise 80% to 99% by weight the abrasive filler substance. The abrasive filler substance is selected from the group consisting of abrasive silica, calcium carbonate, talc, kaolin and mixtures thereof. The microspheres are relatively fragile, in which they break directly upon contact with the teeth during chewing, releasing the abrasive substances at the site at which they are to perform their abrasive action (pg. 2, ll. 15-23).

Miskewitz teaches a chewing gum product comprising between 15-80 weight percent gum base and between 1-30 weight percent dispersed particles of an organic-encapsulated alkali metal bicarbonate ingredient (sodium bicarbonate or potassium bicarbonate or mixtures thereof). The encapsulated particles comprise a metal bicarbonate crystallite core matrix and a flavorant ingredient adsorbed on the crystallite surface. In addition to (1) the gum base and (2) the dispersed particles of organic-encapsulated alkali metal bicarbonate, the chewing gum product can further include components(3)-(9): (3) alkali bicarbonate power, (4) water soluble bulking material, (5)

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colorant, (6) 0-20 weight percent of an abrasive ingredient, (7) surfactant ingredient, (8) fluoridating ingredient and (9) glycerin or lecithin or a mixture thereof. Miskewitz further teaches the chewing gum can contain unencapsulated alkali metal bicarbonate (col. 5, l. 53 to col. 6, l. 3) in addition to the encapsulated alkali metal bicarbonate. It is an object of Miskewitz to provide a chewing gum product with encapsulated alkali metal bicarbonate/flavorant ingredients in which the encapsulated ingredients are sustained-released over a prolonged period under gum mastication conditions (col. 8, ll. 11-14). It is noted that sodium and potassium carbonate are readily water-soluble.

The Examiner asserts Miskewitz teaches an abrasive material, i.e. silica, can be included in addition to the bicarbonate component, therefore rendering it obvious to combine the bicarbonate and silica, which combination would then be encapsulated with the alginate salt. Applicants respectfully disagree with this assertion. Miskewitz teaches the addition of 0-20 weight percent of abrasive ingredients to the overall chewing gum product (col. 6, ll. 59-65). There is no teaching or disclosure whatsoever in Miskewitz to indicate the abrasive ingredients are encapsulated. Miskewitz teaches only the metal bicarbonate and flavorant as being encapsulated which is evident in Examples I-IV.

Yang teaches a chewing gum with long-lasting, uniform flavor levels. The invention concerns a delivery system comprising an insolubilized active ingredient and a cross-linked alginate matrix entrapping the insolubilized active ingredients. Yang

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teaches flavoring agents, drug, coloring agents, sweetening agents and bulking agents as insolubilized active ingredients (claims 4, 15 and 19).

The Examiner asserts that it would have been obvious to use a cross-linked alginate as the alginate salt in Miskewitz since cross-linked alginates have been used to encapsulate insolublized active ingredients in chewing gum compositions, as evidenced by Yang.

According to M.P.E.P. § 2143:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

As presented above, Miskewitz teaches encapsulated alkali metal carbonate/flavorant, which is clearly water-soluble and does not make obvious the water insoluble abrasive filler substance as required by claim 1. It is clear that Miskewitz makes use of encapsulated alkali metal bicarbonate in order to delay its solubilization. Furthermore, there no suggestion or teaching by Miskewitz to be motivated to

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encapsulate an abrasive water insoluble substance as there is no suggestion of using a high loading of abrasive water insoluble substance to make the encapsulated particles fragile in order to release the abrasive as a result of mechanical rupture.

The present invention makes use of a water insoluble cross-linked alginate, together with a high loading of the abrasive substance in the microspheres. As a result of the combined feature, the microspheres are relatively fragile and break up directly upon contact with the teeth during chewing, thereby releasing the abrasive substance. The effectiveness of these features is presented in the above referenced article.

Accordingly the claimed invention does not rely on solubilization of the encapsulating polymer, but specifically aims at achieving mechanical rupture of the microspheres, in order to achieve an improved abrasive action of the released abrasive.

Neither Miskewitz nor Yang addresses the above mechanical rupture of microspheres to achieve an improved abrasive action. Miskewitz and Yang are aimed at controlled release of their encapsulated particles.

Miskewitz fails to teach or suggest an encapsulated water insoluble abrasive filler substance in which the abrasive filler substance is 80-99 % by weight the microsphere. Therefore, Miskewitz fails to render claim 10 obvious. Furthermore, Yang does not remedy the deficiencies of Miskewitz. Withdrawal of the rejection is respectfully requested.

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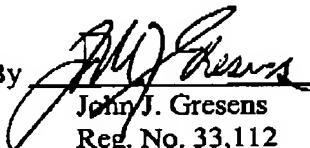
Claims 11-15 and 17 depend either directly or indirectly from claim 10. For the reasons discussed above for claim 10, withdrawal of the rejection is respectfully requested.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the undersigned attorney, John J. Gresens, Reg. No. 33,112, at (612)371.5265.

Respectfully submitted,

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